

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Meulenberg et al.

Serial No.: 10/750,409

Filed: December 30, 2003

For: INFECTIOUS CLONES OF RNA VIRUSES AND VACCINES AND DIAGNOSTIC ASSAYS DERIVED

**THEREOF** 

**Examiner:** To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 2183-4041.4US

#### CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

February 10, 2004

Date

Betty Vowles

Name (Type/Print)

#### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

### U.S. Patent Documents

U.S. Patent No.	Publication Date	<u>Patentee</u>
#US-3,137,631	06/1964	Soloway
#US- 3,959,457	05/1976	Speaker et al.
#US- 4,015,100	03/1997	Gnanamuthu et al.
#US- 4,205,060	05/1980	Monsimer et al.
#US- 4,452,747	06/1984	Gersonde et al.
#US- 4,606,940	08/1986	Frank et al.
#US- 4,744,933	05/1988	Rha et al.
#US- 4,921,706	05/1990	Roberts et al.
#US- 4,927,637	05/1990	Morano et al.
#US- 4,944,948	07/1990	Uster et al.
#US- 5,008,050	04/1991	Cullis et al.
#US- 5,009,956	04/1991	Baumann
#US- 5,132,117	07/1992	Speaker et al.
#US- 6,268,199	07/2001	Meulenberg et al.
#US- 6,110,467	08/2001	Paul et al.
#US-5,476,778	12/1995	Chladek et al.
#US- 5,510,258	4/1996	Sanderson et al.
#US- 5,620,691	4/1997	Wensvoort et al.
#US- 5,677,429	10/1997	Benfield
#US- 5,683,865	11/1997	Collins et al.
#US- 5,690,940	11/1997	Joo
#US- 5,695,766	12/1997	Paul et al.
#US- 5,840,563	11/1998	Chladek et al.
#US- 5,846,805	12/1998	Collins et al.
#US - 5,998,601	12/1999	Murtaugh et al.
#US- 6,197,310	3/2001	Wensvoort et al.
#US- 6,251,397	6/2001	Paul et al.
#US - 6,455,245	9/2002	Wensvoort et al.
#US- 6,495,138	12/2002	van Nieuwstadt et al.
#US- 6,500,662 B1	12/2002	Calvert et al.
#US- 2003/0157689 A1	08/2003	Calvert et al.

### Foreign Patent Documents

Document No.	Publication Date	Patentee
WED 0 440 010 41	00/1001	Schwiz, Serum- & Impfinstitut
#EP 0 440 219 A1	08/1991	Bern
W0.500.504	0/4.000	Boehringer Ingelheim Animal
#0 529 584	8/1992	Health Inc.
UTD 0505426 A 0	10/1000	Iowa State University
#EP 0595436 A2	10/1983	Research Foundation, Inc.
#EP 0732340	3/1996	Akzo Nobel N.V.
#EP 0 835 930 A1	04/1998	Akzo Nobel N.V.
#ED 0020012 A1	5/1000	Instituut voor Dierhouderij en
#EP 0839912 A1	5/1998	Diergezondheid (ID-DLO)
#WO 93/06211	04/1993	Benfield
#WO 93/14196	07/1993	Brun
#WO 94/18311	08/1994	Iowa State University
#WO 94/16311	06/1994	Research Foundation Inc.
#WO 95/28227	10/1995	Children's Hospital of
#WO 93/2622/	10/1993	Philadelphia
#WO 96/36356	11/1996	Boehringer Ingelheim
#WO 90/30330	11/1990	Corporation
#WO 96/40932	12/1996	Halbur
#0 587 780	3/1994	Stichting Centraal
#0 367 760	3/1994	Diergeneeskundig Instituut
#0 610 250	12/1995	Akzo Nobel N.V.
#2 282 881	4/1995	Cyanamid Iberica S A
#2289279	11/1995	Cyanamid Iberica S A
#WO 92/21375	12/1992	Stichting Centraal
π <b>νν</b> Ο <i>92</i> (21313	12/1772	Diergeneeskundig Instituut

#WO 93/03760	3/1993	Collins et al.
#370 06/04010	2/1996	Regents of the University of
#WO 96/04010	2/1990	Minnesota
#WO 96/06619	3/1996	Paul et al.
#WO 97/31651	9/1997	Schering Corporation
#WO 98/18933	5/1998	Bos-De Ruijter
		Stichting Instituut voor
#WO 98/50426	11/12/1998	Dierhouderij en
		Diergezondheid
#WO 98/55626	12/1998	Origen, Inc.
UNIO 00/52797	00/2000	Stichting Dienst
#WO 00/53787	09/2000	Landbouwkundig Onderzoek
		ID-Lelystad, Instituut voor
#WO 02/095040 A1	11/2002	Dierhouderij en
		Diergezondheid B.V.
WO 93/07898	04/1993	Akzo N.V.

#### Other Documents

#"Advances in Veterinary Virology 2", Veterinary Microbiology, 33 (1992), pp. 185-193.

#Abstracts of Papers Presented at the 71st Annual Meeting of the Conference of Research

Workers in Animal Disease, No.'s 1-6, Nov, 5-6, 1990, 2 pages.

#Beale AJ, "Vaccines and antiviral drugs", Principles of bacteriology, virology and

immunity, Vol. 4, Ch. 86, pp. 147-161.

#Boursnell et al., "Completion of the Sequence of the Genome of the Coronavirus Avian Infectious Bronchitis Virus", Journal of General Virology 68, 1986, pp. 57-77.

#Brinton MA, "Lactate Dehydrogenase-Elevating, Equine Arteritis and Lelystad Viruses", Encyclopedia of Virology, Vol. 2, pp. 763-771.

#Christianson et al., "Experimental reproduction of swine infertility and respiratory syndrome in pregnant sows", Am J Vet Res., Vol. 53, No. 4, April 1992, pp. 485-488.

#Christianson et al., "Porcine reproductive and respiratory syndrome: A review", Swine Health and Production, Vol. 2, No. 2, pp. 10-28, March and April, 1994.

#Collins et al., "Isolation of swine infertility and respiratory syndrome virus (isolate ATCC VR-2332) in North America and experimental reproduction of the disease in gnotobiotic pigs", J Vet Diagn Invest, 4:117-126 (1992).

#Dea et al., "Swine reproductive and respiratory syndrome in Quebec: Isolation of an enveloped virus serologically-related to Lelystad virus.", Can. Vet. Journal, Vol. 33, pp. 801-808.

#Den Boon et al., "Equine Arteritis Virus Is Not a Togavirus but Belongs to the Coronaviruslike Superfamily", Journal of Virology, Vol. 65, No. 6, pp. 2910-2920, 1991.

#de Vries et al., "All subgenomic mRNAs of equine arteritis virus contain a common leader sequence", Nucleic Acids Research, Vol. 18, No. 11, 1990, pp. 3241-3247.

#Duran et al., "Recombinant Baculovirus Vaccines Against Porcine Reproductive And Respiratory Syndrome (PRRS)", <u>Abstracts PRRS</u>, August 9th to 10th, 1995, Copenhagen, Denmark, 2 pages.

#Dykhuizen et al., "Determining the Economic Impact of the 'New' Pig Disease", <u>Porcine</u>
Reproductive and Respiratory Syndrome, A Report on the Seminar Held in Brussels on 4-5
November 1991 and Organized by the European Commission, pp. 53-60.

#Fenner et al., "Viral Genetics and Evolution", Veterinary Virology, Ch. 5, pp. 89-95.

#Fenner et al., "Immunization against Viral Diseases", <u>Veterinary Virology</u>, Ch. 14, pp. 265-271.

#Godeny et al., "Map Location of Lactate Dehydrogenase-Elevating Virus (LDV) Capsid Protein (Vp1) Gene", Virology 177, (1990), pp. 768-771 (1990).

#Godeny et al., "The 3' Terminus of Lactate Dehydrogenase-Elevating Virus Genome RNA Does Not Contain Togavirus or Flavivirus Conserved Sequences", <u>Virology 172</u>, pp. 647-650 (1989).

#Goyal et al., "Porcine reproductive and respiratory syndrome", <u>J. Vet. Diagn. Invest.</u>, Vol. 3, pp. 656-664.

#Joo et al., "Encephalomyocarditis Virus As A Potential Cause For Mystery Swine Disease", <u>Livestock Conservation Institute</u>, Denver, CO, pp. 62-66, October 6, 1990.

#Keffaber, K., "Reproductive Failure of Unknown Etiology", <u>AASP Newsletter</u>, Vol. 1, Number 2, September-October 1989, pp. 1, 4-5, 8-10.

#Kuo et al., "A Nested Set of Eight RNAs Is Formed in Macrophages Infected with Lactate Dehydrogenase-Elevating Virus", <u>Journal of Virology</u>, Vol. 65, No. 9, Sept. 1991, pp. 5118-5123.

#Loula, Timothy, "Mystery Pig Disease", <u>Agri-Practice</u>, Vol. 12, No. 1, pp. 29-34, Jan/Feb 1991, 7 pages.

#Mc Cullough et al., "9. Experimental Transmission Of Mystery Swine Disease", <u>The New Pig Disease Porcine Respiration And Reproductive Syndrome</u>, A report on the seminar/workshop held in Brussels on 29-30 April, 1991, pp. 46-52.

#Meredith MJ, "Porcine Reproductive and Respiratory Syndrome (PRRS)", Pig Disease Information Center, 1st North American Edition, University of Cambridge, pp. 1-57, August 1994.

#Meulenberg et al., Localization and Fine Mapping of Antigenic Sites on the Nucleocapsid Protein N of Porcine Reproductive and Respiratory Syndrome Virus with Monoclonal Antibodies, Virology, 1998, vol. 252, pp. 106-114.

#Meulenberg et al., Posttranslational Processing and Identification of a Neutralization Domain of the CP<sub>4</sub> Protein Encoded by ORF4 of Lelystad Virus, Journal of Virology, August 1997, pp. 6061-67, Vol. 71. No. 3.

#Moormann et al., "Molecular Cloning and Nucleotide Sequence of Hog Cholera Virus Strain Brescia and Mapping of the Genomic Region Encoding Envelope Protein E1<sup>1</sup>", <u>Virology</u> 177, pp. 184-198 (1990).

#Morrison et al., "Brief Communications Serologic evidence incriminating a recently isolated virus (ATCC VR-2332) as the cause of swine infertility and respiratory syndrome (SIRS)", <u>J Vet Diagn Invest</u>, 4:186-188 (1992).

#Murphy et al., "Immunization Against Virus" in <u>Virology</u> 2nd ed., Vol. 1, Fields et al. eds. Raven Press, NY, 1990, pp. 469-502.

#Nieuwstadt et al., Proteins Encoded by Open Reading Frames 3 and 4 of the Genome of Lelystad Virus (Arteriviridae) Are Structural Proteins of the Virion, Journal of Virology, Jul. 1996, Vol. 70, No. 7, pp. 4767-4772.

#Notice of Opposition by Akzo Nobel against European Patent No. 0 587 780, November 28, 1995, EP.

#Notice of Opposition by Cyandmid Iberica against European Patent No. 0 587 780, November 28, 1995, EP.

#Pol et al., "Pathological, ultrastructural, and immunohistochemical changes caused by Lelystad virus in experimentally induced infections of mystery swine disease (synonym: porcine epidemic abortion and respiratory syndrome (PEARS))", <u>The Veterinary Quarterly</u>, Vol. 13, No. 3, July 1991, pp. 137-143.

#Polson DD, "Answers to Your Questions on PRRS", NOBL Laboratories, 18 pages.

#Polson DD, "RespPRRS A PRRS Vaccine Review", NOBL Laboratories, 22 pages.

#Polson et al., "An evaluation of the financial impact of Porcine Reproductive and Respiratory Syndrome (PRRS) in nursery pigs", <u>Proceedings of the 13th International Pig Veterinary Society Congress</u>, p. 31, June 1994.

#Polson et al., "Financial Implications of Mystery Swine Disease (MSD)", pp. 8-28.

#Response to Opposition to European Patent No. 0 587 780, August 30, 1996.

#"Revision of the taxonomy of the Coronavirus, Torovirus and Arterivirus genera", <u>Arch Virol</u>, Vol. 135, pp. 227-239, 1994.

#Saif L.S., "Coronavirus immunogens", Veterinary Microbiology, 37:285-297, 1993.

#Scott F.W., "Immunization Against Feline Coronaviruses", <u>Adv. Exp. Med. Biol.</u>, 218:569-576, 1987.

#Snijder et al., "The carboxyl-terminal part of the putative Berne virus polymerase is expressed by ribosomal frameshifting and contains sequence motifs which indicate that toro- and coronaviruses are evolutionarily related", <u>Nucleic Acids Research</u>, Vol. 18, No. 15, pp. 4535-4542, 1990.

#Terpstra et al., "Experimental reproduction of porcine epidemic abortion and respiratory syndrome (mystery induced infections of mystery swine disease (synonym: porcine epidemic abortion and respiratory syndrome (PEARS)", The Veterinary Quarterly, Vol. 13, No. 3, July 1991, pp. 131-136.

#Timony PJ, "Equine Viral Arteritis", <u>Manual of Standards for Diagnostic Tests and Vaccines</u>, pp. 493-499, 1992.

#van Zijl et al., "Live Attenuated Pseudorabies Virus Expressing Envelope Glycoprotein E1 of Hog Cholera Virus Protects Swine against both Pseudorabies and Hog Cholera", <u>Journal of Virology</u>, Vol. 65, No. 5, May 1991, pp. 2761-2765.

#Visser, Nicolaas, "Declaration Of Dr. N. Visser", November 14, 1995, pp. 1-11.

#von V. F. Ohlinger et al., "Der »Seuchenhafte Spatabort beim Schwein« - Ein Beitrag zur Atiologie des »»Porcine Reproductive and Respiratory Syndrome (PRRS)««", <u>Tierarztl.</u> <u>Umschau 46</u>, pp. 703-708 (1991).

#Waltner-Toews et al., "A Field Trial to Evaluate the Efficacy of a Combined Rotavirus-Coronavirus/Escherichia coli Vaccine in Dairy Cattle", Can J. Comp. Med., 49:1-9, 1985.

#Wardley et al., "The Host Response to African Swine Fever Virus", <u>Prog. Med. Virol.</u>, Vol. 34, pp.180-192 (1987).

#Wenswoort et al., "Antigenic comparison of Lelystad virus and swine infertility and respiratory syndrome (SIRS) virus", <u>J Vet Diagn Invest</u>, Vol. 4, pp. 134-138, 1992.

#Wensvoort et al., "Blue ear" disease, <u>The Veterinary Record</u>, Vol. 128, No. 128, June 15, 1991, column 1, letter, page 574.

#Wensvoort et al., "Mystery swine disease in the Netherlands: the isolation of Lelystad virus", The Veterinary Quarterly, Vol. 13, No. 3, July 1991, pp. 121-130.

#Wensvoort et al., "The Porcine Reproductive and Respiratory Syndrome; Characteristics and diagnosis of the causative virus", <u>Veterinary Biotechnology Newsletter</u>, Vol. 3, pp. 113-120, 1993.

#Yoon et al., "Isolation of a cytophathic virus from weak pigs on farms with a history of swine infertility and respiratory syndrome", <u>J. Vet Diagn Invest</u>, 4:139-143 (1992).

#ALLENDE, R. et al., North American and European Porcine Reproductive and Respiratory Syndrome Viruses Differ in Non-Structural Protein Coding Regions, Journal Gen. Virol. 80 (Pt 2), 307-315 (1999).

#ANDREYEV VG., et al. Abstract, Genetic variation and phylogenetic relationships of 22 porcine reproductive and respiratory syndrome virus (PRRSV) fields strains based on sequence analysis of open reading frame 5, Arch Virol 142:993-1001, 1997.

#BRAMEL-VERHEIJE et al., Expression of a Foreign Epitope by Porcine Reproductive and Respiratory Syndrome Virus, 2000, Virology, pp. 380-389, Vol. 278.

#BOYER, J.C. et al., Infectious Transcripts and cDNA Clones of RNA Viruses, Virology, 1994, pp. 415-426, Vol. 198.

#CHEN, Z., et al., Determination of the 5' end of the lactate dehydrogenase-elevating virus genome by two independent approaches, J. Gen. Virol., 1994, pp. 925-930, Vol. 75.

#FROLOV et al., Alphavirus-based expression vectors: Strategies and applications, Proceedings of the National Academy of Sciences, 1996, pp. 11371-11377, Vol. 93.

#KAPUR, V., et al., Abstract, Genetic Variation in Porcine reproductive and Respiratory Syndrome Virus Isolates in the Midwestern United States, Journal of Gen. Virol. 77, pp. 1271-1276 (1996).

#KWANG, Jimmy, et al., Abstract, Cloning, Expression, and Sequence Analysis of the OrF4 Gene of the Porcine Reproductive and Respiratory Syndrome Virus MN-1b, J Vet Diagn. Invest 6, pp. 293-296 (1994).

#MARDASSI, H., et al., Abstract, Molecular Analysis of the ORF's 3 to 7 of Porcine Reproductive and Respiratory Syndrome Virus, Quebec Reference Strain, Arch Virol 140, pp. 1405-1418 (1995).

#MENG, Xiang-Jin, Abstract, Molecular Cloning and Nucleotide Sequencing of the 3'-Terminal Genomic RNA of the Porcine Reproductive and Respiratory Syndrome Virus, Journal of General Virology 75, pp. 1795-1801 (1994).

#MEULENBERG et al., Characterization of Proteins Encoded by ORFs 2 to 7 of Lelystad Virus, Virology, 1995, pp. 155-63, Vol. 206.

#MEULENBERG, J.J. M., et al., Lelystad Virus, the Causative Agent of Porcine Epidemic Abortion and Respiratory Syndrome (PEARS), Is Related to LDV and EAV, 1993, Virology, pp. 62-72, Vol. 192.

#MEULENBERG, J. J. M., et al., Infectious transcripts from cloned genome-length cDNA of porcine reproductive and respiratory syndrome virus. J. Virol. 72(1):pp. 380-387, 1998.

#MEULENBERG, J.J.M., et al., Abstract, "An infectious cDNA clone of Porcine Reproductive and Respiratory Syndrome Virus" Chapter 24, pp. 199-206 Coronaviruses and Arteriviruses (Advances in Experimental Medicine and Biology, vol. 440), 1998.

#KIM HS., et al., Abstract, Enhanced replication of porcine reproductive and respiratory syndrome (PRRS) virus in a homogeneous subpopulation of MA-104 cell line, Arch Virol 133:477-483, 1993.

#KREUTZ, L.C., Abstract, "Cellular membrane factors are the major determinants of porcine reproductive and respiratory syndrome virus tropism," Virus Research 53:121-128, 1998.

#MENG XJ., et al., Abstract, Phylogenetic analyses of the putative M (ORF 6) and N (ORF 7) genes of porcine reproductive and respiratory syndrome virus (PRRSV): implication for the existence of two genotypes of PRRSV in the U.S.A. and Europe, Arch Virol 140:745-755, 1995.

#MOORMANN et al., Infectious RNA Transcribed from an Engineered Full-Length cDNA Template of the Genome of a Pestivirus, Journal of Virology, Feb. 1996, pp. 763-70, Vol. 70, No. 2.

#MOROZOV I., et al., Abstract, Sequence analysis of open reading frames (ORFs) 2 to 4 of a U.S. isolate of porcine reproductive and respiratory syndrome virus, Arch Virol 140:1313-1319, 1995.

#MURTAUGH, M. P., et al., Abstract, Comparison of the Structural Protein Coding Sequences of the VR-2332 and Lelystad virus strain of the PRRS virus, Journal Arch. Virol. 140(8), pp. 1451-1460 (1995).

#NELSEN, C. J., et al., Porcine reproductive and respiratory syndrome virus comparison: Divergent evolution on two continents. J. Virol. 73 (1): pp. 270-280, 1999.

#PCT International Preliminary Examination Report, PCT/NL 00/00152, dated May 29, 2001.

#PCT International Search Report, PCT/NL 00/00152, dated July 6, 2000, 3 pages.

#ROSSOW KD., Abstract, Porcine Reproductive and Respiratory Syndrome, Vet Pathol 35:1-20 (1998).

#SNIJDER et al., The molecular biology of arteriviruses, Journal of General Virology, 1998, pp. 961-79, Vol. 79.

#SUAREZ P., et al., Abstract, Phylogenetic relationships of European strains of porcine reproductive and respiratory syndrome virus (PRRSV) inferred from DNA sequences of putative ORF-5 and ORF-7 genes, Virus Research 42:159-165, 1996.

#TERPSTRA C., et al., Abstract, Experimental reproduction of porcine epidemic abortion and respiratory syndrome (mystery swine disease) by infection with Lelystad virus: Koch's postulates fulfilled, The Veterinary Quarterly, vol. 13, No. 3, pp. 131-136, Jul. 1991.

#VAN DINTEN, L.D. et al., 1997, Proc. Natl. Acad. Sci. USA, 94(3):991-996.

#ZIMMERMAN JJ., et al., Abstract, General overview of PRRSV: A perspective from the United States, Veterinary Microbiology 55:187-196, 1997.

#PCT International Preliminary Examination Report, PCT/NL02/00314, dated August 26, 2003, 6 pages.

#NC\_001961, Porcine reproductive and respiratory syndrome virus, complete genome.

#AF066183, Porcine reproductive and respiratory syndrome virus RespPRRS MLV, complete genome.

#AF325691, Porcine reproductive and respiratory syndrome virus isolate NVSL 97-7985 IA 1-4-2, complete genome.

#AF176348, Porcine reproductive and respiratory syndrome virus isolate PA8 complete genome.

#AF331831, Procine reproductive and respiratory syndrome virus BJ-4, complete genome.

#AE005172, Arabidopsis thaliana chromosome 1, top arm complete sequence.

#NC\_002534, Lactate dehydrogenase-elevating virus, complete genome.

#U87392, Porcine reproductive and respiratory syndrome virus strain VR-2332, complete genome.

#M96262, Lelystad virus, complete genome.

#AF184212, Porcine reproductive and respiratory syndrome virus strain SP, complete genome.

#AF159149, Porcine reproductive and respiratory syndrome virus isolate MLV RespPRRS/Repro, complete genome.

#AF046869, Porcine reproductive and respiratory syndrome virus isolate 16244B, 2/18/97 (Nebraska)pass.3, complete genome.

#U15146, Lactate dehydrogenase-elevating virus Plagemann strain, complete genome.

#VIIIth International Symposium on Nidoviruses (Corona and Arteriviruses), May 20-25, 2000.

MENGELING et al., Mystery Pig Disease: Evidence and considerations for its etiology, In: Proceedings of the Mystery Swine Disease Committee Meeting, October 6, 1990, Denver, Colorado, Livestock Conservation Institute, Madison, WI, USA.

ROTTIER et al., Predicted membrane topology of the coronavirus protein E1, Biochemistry, 1986, pp. 1335 1339, Vol. 25.

SETHNA et al., Coronavirus subgenomic minus-strand RNAs and the potential for mRNA replicons, Proc. Natl. Acad. Sci. 1989, USA, pp. 5626 5630, Vol. 86.

SPAAN et al., Coronaviruses: structure and genome expression, J. Gen. Virol., 1988, pp. 2939 2952, Vol. 69.

VRIES et al., All subgenomic mRNAs of equine arteritis virus contain a common leader sequence, Nucleic Acids Res., 1990, pp. 3241-3247, Vol. 18.

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/874,626

Filed: 6/5/2001

For: INFECTIOUS CLONES OF RNA VIRUSES AND VACCINES AND DIAGNOSTIC ASSAYS DERIVED THEREOF, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.:

2183-4041.1US

Serial No.:

6/5/2001

Filing Date:

09/874,626

Title:

INFECTIOUS CLONES OF RNA VIRUSES AND VACCINES

AND DIAGNOSTIC ASSAYS DERIVED THEREOF

Attorney Docket No.: 2183-5051US

Serial No.:

09/948,747

Filing Date:

9/7/2001

Title:

PRRSV VACCINE

Attorney Docket No.:

2183-2643.3US

Serial No.:

10/226,065

Filing Date:

8/21/2002

Title:

CAUSATIVE AGENT OF THE MYSTERY SWINE DISEASE,

VACCINE COMPOSITIONS AND DIAGNOSTIC KITS

Attorney Docket No.:

2183-5584US

Serial No.:

10/300,699

Filing Date:

11/19/2002

Title:

CHIMERIC ARTERIVIRUS-LIKE PARTICLES

Attorney Docket No.: 2183-5911US

Serial No.:

10/407,822

Filing Date:

4/4/2003

Title:

ADAPTATION SITES OF PORCINE REPRODUCTIVE AND

RESPIRATORY SYNDROME VIRUS

Attorney Docket No.: 2183-2643.4US

Serial No.:

10/737,658

Filing Date:

12/16/2003

Title:

CAUSATIVE AGENT OF THE MYSTERY SWINE DISEASE,

VACCINE COMPOSITIONS AND DIAGNOSTIC KITS

Attorney Docket No.:

2183-4041.2US

Serial No.:

10/745,949

Filing Date:

12/23/2003

Title:

INFECTIOUS CLONES OF RNA RIVUSES AND VACCINES

AND DIAGNOSTIC ASSAYS DERIVED THEREOF

Attorney Docket No.: 2183-4041.3US

Serial No.:

10/750,410 12/30/2003

Filing Date:

Title:

INFECTIOUS CLONES OF RNA VIRUSES AND VACCINES

AND DIAGNOSTIC ASSAYS DERIVED THEREOF

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Respectfully submitted,

G. Scott Dorland, Ph.D.

Registration No. 51,622 Attorney for Applicant(s)

TRASKBRITT, P.C.

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

Date: February 10, 2004

GSD/bv

Enclosures: Form PTO/SB/08

Document in ProLaw

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number 10/750,409

Filing Date December 30, 2003

First Named Inventor Meulenberg et al.

Group Art Unit To be assigned

Examiner Name To be assigned

Attorney Docket Number 2183-4041.4US

Sheet 1 of 11

	1	Document Number	Bublication Date	Name of Patentee or Applicant of	Pages Columns Lines When Pulsary	
Examiner Initials *	Cite No.1	Cite No.¹  Number - Kind Code² (if known)  Number - Kind Code² (if known)		Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		#US-3,137,631	06/1964	Soloway		
		#US- 3,959,457	05/1976	Speaker et al.		
•		#US- 4,015,100	03/1997	Gnanamuthu et al.		
		#US- 4,205,060	05/1980	Monsimer et al.		
		#US- 4,452,747	06/1984	Gersonde et al.		
		#US- 4,606,940	08/1986	Frank et al.		
		#US- 4,744,933	05/1988	Rha et al.		
		#US- 4,921,706	05/1990	Roberts et al.	-	
		#US- 4,927,637	05/1990	Morano et al.		
		#US- 4,944,948	07/1990	Uster et al.		
		#US- 5,008,050	04/1991	Cullis et al.		
		#US- 5,009,956	04/1991	Baumann		
		#US- 5,132,117	07/1992	Speaker et al.		
		#US- 6,268,199	07/2001	Meulenberg et al.		
	1	#US- 6,110,467	08/2001	Paul et al.		

		FOREIGN P	ATENT DOCU	MENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>3</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т <sup>б</sup>
		#EP 0 440 219 A1	08/1991	Schwiz, Serum- & Impfinstitut Bern		
		#0 529 584	8/1992	Boehringer Ingelheim Animal Health Inc.		
		#EP 0595436 A2	10/1983	lowa State University Research Foundation, Inc.		
		#EP 0732340	3/1996	Akzo Nobel N.V.		
		#EP 0 835 930 A1	04/1998	Akzo Nobel N.V.		
		#EP 0839912 A1	5/1998	Instituut voor Dierhouderij en Diergezondheid (ID- DLO)		
		#WO 93/06211	04/1993	Benfield		
		#WO 93/14196	07/1993	Brun		
		#WO 94/18311	08/1994	lowa State University Research Foundation Inc.		
		#WO 95/28227	10/1995	Children's Hospital of Philadelphia		
		#WO 96/36356	11/1996	Boehringer Ingelheim Corporation		
		#WO 96/40932	12/1996	Halbur		
Examiner Signature			Date Conside	ered		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \(^1\) Applicant's unique citation designation number (optional) \(^2\) See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. \(^3\) Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \(^4\) For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \(^5\) Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \(^6\) Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

Signature

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number 10/750,409

Filing Date December 30, 2003

First Named Inventor Meulenberg et al.

Group Art Unit To be assigned

Examiner Name To be assigned

Attorney Docket Number 2183-4041.4US

(use as many sheets as necessary) Ex

**U.S. PATENT DOCUMENTS** Name of Patentee or Applicant of Document Number Publication Date Pages, Columns, Lines, Where Relevant Examiner Cite Cited Document MM-DD-YYYY Passages or Relevant Initials \* No. Number - Kind Code<sup>2</sup> (if known) Figures Appear #US-5,476,778 12/1995 Chladek et al. #US- 5,510,258 4/1996 Sanderson et al #US- 5,620,691 4/1997 Wensvoort et al #US- 5,677,429 10/1997 Benfield #US- 5,683,865 11/1997 Collins et al. #US- 5,690,940 11/1997 Joo #US- 5,695,766 12/1997 Paul et al #US- 5,840,563 11/1998 Chladek et al #US- 5,846,805 12/1998 Collins et al. #US- 5,998,601 12/1999 Murtaugh et al. #US-6,197,310 3/2001 Wensvoort et al. #US-6,251,397 6/2001 Paul et al. 9/2002 Wensvoort et al. #US-6,455,245 #US-6,495,138 12/2002 van Nieuwstadt et al. 12/2002 #US- 6,500,662 B1 Calvert et al. #US- 2003/0157689 A1 8/2003 Calvert et al. FOREIGN PATENT DOCUMENTS

		Foreign Patent Document	Publication		Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Total I Total		Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		#0 587 780	3/1994	Stichting Centraal Diergeneeskundig Instituut		
		#0 610 250	12/1995	Akzo Nobel N.V.		
		#2 282 881	4/1995	Cyanamid Iberica S A		
		#2289279	11/1995	Cyanamid Iberica S A		
		#WO 92/21375	12/1992	Stichting Centraal Diergeneeskundig Instituut		
		#WO 93/03760	3/1993	Collins et al.		
	-	#WO 96/04010	2/1996	Regents of the University of Minnesota		
		#WO 96/06619	3/1996	Paul et al.		
		#WO 97/31651	9/1997	Schering Corporation		
		#WO 98/18933	5/1998	Bos-De Ruijter		
		#WO 98/50426	11/12/1998	Stichting Instituut voor Dierhouderij en Diergezondheid		
		#WO 98/55626	12/1998	Origen, Inc.		
		#WO 00/53787	09/2000	Stichting Dienst Landbouwkundig Onderzoek		
		#WO 02/095040 A1	11/2002	ID-Lelystad, Instituut voor Dierhouderij en Diergezondheid B.V.		
		WO 93/07898	04/1993	Akzo N.V.		
Examiner			Dat	e		•

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate

Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.





PTO/SB/08B(10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute f	For form 1449A/PTO				Complete if Known
INEO	IDRA A TOTAL		CCI OCUDE	Application Number	10/750,409
			SCLOSURE	Filing Date	December 30, 2003
STAT	EMENT B	ΥA	PPLICANT	First Named Inventor	Meulenberg et al.
				Group Art Unit	To be assigned
	(use as many she	ets as	necessary)	Examiner Name	To be assigned
Sheet	3	of	11	Attorney Docket Number	2183-4041.4US

	,	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#"Advances in Veterinary Virology 2", Veterinary Microbiology, 33 (1992), pp. 185-193.	
		#Abstracts of Papers Presented at the 71st Annual Meeting of the Conference of Research Workers in Animal Disease, No.'s 1-6, Nov, 5-6, 1990, 2 pages.	
		#Beale AJ, "Vaccines and antiviral drugs", Principles of bacteriology, virology and immunity, Vol. 4, Ch. 86, pp. 147-161.	
		#Boursnell et al., "Completion of the Sequence of the Genome of the Coronavirus Avian Infectious Bronchitis Virus", Journal of General Virology 68, 1986, pp. 57-77.	
		#Brinton MA, "Lactate Dehydrogenase-Elevating, Equine Arteritis and Lelystad Viruses", Encyclopedia of Virology, Vol. 2, pp. 763-771.	
		#Christianson et al., "Experimental reproduction of swine infertility and respiratory syndrome in pregnant sows", Am J Vet Res., Vol. 53, No. 4, April 1992, pp. 485-488.	
		#Christianson et al., "Porcine reproductive and respiratory syndrome: A review", Swine Health and Production, Vol. 2, No. 2, pp. 10-28, March and April, 1994.	
		#Collins et al., "Isolation of swine infertility and respiratory syndrome virus (isolate ATCC VR-2332) in North America and experimental reproduction of the disease in gnotobiotic pigs", J Vet Diagn Invest, 4:117-126 (1992).	-
		#Dea et al., "Swine reproductive and respiratory syndrome in Quebec: Isolation of an enveloped virus serologically-related to Lelystad virus.", Can. Vet. Journal, Vol. 33, pp. 801-808.	
		#Den Boon et al., "Equine Arteritis Virus Is Not a Togavirus but Belongs to the Coronaviruslike Superfamily", Journal of Virology, Vol. 65, No. 6, pp. 2910-2920, 1991.	
		#de Vries et al., "All subgenomic mRNAs of equine arteritis virus contain a common leader sequence", Nucleic Acids Research, Vol. 18, No. 11, 1990, pp. 3241-3247.	

Examiner	Date	1
Signature	Considered	J

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO			Complete if Known		
INCODA A TION DIGGL OCUDE				Application Number	10/750,409
INFORMATION DISCLOSURE				Filing Date	December 30, 2003
STATEMENT BY APPLICANT		First Named Inventor	Meulenberg et al.		
				Group Art Unit	To be assigned
	(use as many sh	eets as i	iecessary)	Examiner Name	To be assigned
Sheet	4	of	11	Attorney Docket Number	2183-4041.4US

	Т	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#Duran et al., "Recombinant Baculovirus Vaccines Against Porcine Reproductive And Respiratory Syndrome (PRRS)", <u>Abstracts PRRS</u> , August 9th to 10th, 1995, Copenhagen, Denmark, 2 pages.	
		#Dykhuizen et al., "Determining the Economic Impact of the 'New' Pig Disease", Porcine Reproductive and Respiratory Syndrome, A Report on the Seminar Held in Brussels on 4-5 November 1991 and Organized by the European Commission, pp. 53-60.	
		#Fenner et al., "Viral Genetics and Evolution", Veterinary Virology, Ch. 5, pp. 89-95.	
		#Fenner et al., "Immunization against Viral Diseases", Veterinary Virology, Ch. 14, pp. 265-271.	
		#Godeny et al., "Map Location of Lactate Dehydrogenase-Elevating Virus (LDV) Capsid Protein (Vp1) Gene", Virology 177, (1990), pp. 768-771 (1990).	
"		#Godeny et al., "The 3' Terminus of Lactate Dehydrogenase-Elevating Virus Genome RNA Does Not Contain Togavirus or Flavivirus Conserved Sequences", Virology 172, pp. 647-650 (1989).	
		#Goyal et al., "Porcine reproductive and respiratory syndrome", <u>J. Vet. Diagn. Invest.</u> , Vol. 3, pp. 656-664.	
		#Joo et al., "Encephalomyocarditis Virus As A Potential Cause For Mystery Swine Disease", <u>Livestock Conservation Institute</u> , Denver, CO, pp. 62-66, October 6, 1990.	
		#Keffaber, K., "Reproductive Failure of Unknown Etiology", <u>AASP Newsletter</u> , Vol. 1, Number 2, September-October 1989, pp. 1, 4-5, 8-10.	-
		#Kuo et al., "A Nested Set of Eight RNAs Is Formed in Macrophages Infected with Lactate Dehydrogenase-Elevating Virus", Journal of Virology, Vol. 65, No. 9, Sept. 1991, pp. 5118-5123.	
		#Loula, Timothy, "Mystery Pig Disease", Agri-Practice, Vol. 12, No. 1, pp. 29-34, Jan/Feb 1991, 7 pages.	

Examiner	Date
Signature	Considered

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

+

<sup>&</sup>lt;sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.





PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substit	tute for form 1449A	/PTO			Complete if Known		
YNIT		ION DI	COL COUDE	Application Number	10/750,409		
INFORMATION DISCLOSURE				Filing Date	December 30, 2003		
STA	ATEMEN	T BY A	PPLICANT	First Named Inventor	Meulenberg et al.		
				Group Art Unit	To be assigned		
(use as many sheets as necessary)				Examiner Name	To be assigned		
Sheet	t 5	of	11	Attorney Docket Number	2183-4041.4US		

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		#Mc Cullough et al., "9. Experimental Transmission Of Mystery Swine Disease", The New Pig Disease Porcine Respiration And Reproductive Syndrome, A report on the seminar/workshop held in Brussels on 29-30 April, 1991, pp. 46-52.	
		#Meredith MJ, "Porcine Reproductive and Respiratory Syndrome (PRRS)", Pig Disease Information Center, 1st North American Edition, University of Cambridge, pp. 1-57, August 1994.	
		#Meulenberg et al., Localization and Fine Mapping of Antigenic Sites on the Nucleocapsid Protein N of Porcine Reproductive and Respiratory Syndrome Virus with Monoclonal Antibodies, Virology, 1998, vol. 252, pp. 106-114.	
-		#Meulenberg et al., Posttranslational Processing and Identification of a Neutralization Domain of the CP <sub>4</sub> Protein Encoded by ORF4 of Lelystad Virus, Journal of Virology, August 1997, pp. 6061-67, Vol. 71. No. 3.	
		#Moormann et al., "Molecular Cloning and Nucleotide Sequence of Hog Cholera Virus Strain Brescia and Mapping of the Genomic Region Encoding Envelope Protein E1 <sup>1</sup> ", <u>Virology 177</u> , pp. 184-198 (1990).	
		#Morrison et al., "Brief Communications Serologic evidence incriminating a recently isolated virus (ATCC VR-2332) as the cause of swine infertility and respiratory syndrome (SIRS)", <u>J Vet Diagn Invest</u> , 4:186-188 (1992).	
		#Murphy et al., "Immunization Against Virus" in <u>Virology</u> 2nd ed., Vol. 1, Fields et al. eds. Raven Press, NY, 1990, pp. 469-502.	
		#Nieuwstadt et al., Proteins Encoded by Open Reading Frames 3 and 4 of the Genome of Lelystad Virus (Arteriviridae) Are Structural Proteins of the Virion, Journal of Virology, Jul. 1996, Vol. 70, No. 7, pp. 4767-4772.	
		#Notice of Opposition by Akzo Nobel against European Patent No. 0 587 780, November 28, 1995, EP.	
		#Notice of Opposition by Cyandmid Iberica against European Patent No. 0 587 780, November 28, 1995, EP.	
		#Pol et al., "Pathological, ultrastructural, and immunohistochemical changes caused by Lelystad virus in experimentally induced infections of mystery swine disease (synonym: porcine epidemic abortion and respiratory syndrome (PEARS))", <u>The Veterinary Quarterly</u> , Vol. 13, No. 3, July 1991, pp. 137-143.	
		#Polson DD, "Answers to Your Questions on PRRS", NOBL Laboratories, 18 pages.	
		#Polson DD, "RespPRRS A PRRS Vaccine Review", NOBL Laboratories, 22 pages.	

Examiner	 Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



<sup>&</sup>lt;sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.





PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute 1	or form 1449A/PTO			Complete if Known			
TAIRO		IDI	COL OCUDE	Application Number	10/750,409		
			SCLOSURE	Filing Date	December 30, 2003		
STAT	EMENT B	YA	PPLICANT	First Named Inventor	Meulenberg et al.		
				Group Art Unit	To be assigned		
	(use as many she	eets as	necessary)	Examiner Name	To be assigned		
Sheet	6	of	11	Attorney Docket Number	2183-4041.4US		

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#Polson et al., "An evaluation of the financial impact of Porcine Reproductive and Respiratory Syndrome (PRRS) in nursery pigs", Proceedings of the 13th International Pig Veterinary Society Congress, p. 31, June 1994.	
		#Polson et al., "Financial Implications of Mystery Swine Disease (MSD)", pp. 8-28.	
		#Response to Opposition to European Patent No. 0 587 780, August 30, 1996.	
		#"Revision of the taxonomy of the Coronavirus, Torovirus and Arterivirus genera", Arch Virol, Vol. 135, pp. 227-239, 1994.	
		#Saif L.S., "Coronavirus immunogens", Veterinary Microbiology, 37:285-297, 1993.	
		#Scott F.W., "Immunization Against Feline Coronaviruses", Adv. Exp. Med. Biol., 218:569-576, 1987.	
		#Snijder et al., "The carboxyl-terminal part of the putative Berne virus polymerase is expressed by ribosomal frameshifting and contains sequence motifs which indicate that toro- and coronaviruses are evolutionarily related", Nucleic Acids Research, Vol. 18, No. 15, pp. 4535-4542, 1990.	
		#Terpstra et al., "Experimental reproduction of porcine epidemic abortion and respiratory syndrome (mystery induced infections of mystery swine disease (synonym: porcine epidemic abortion and respiratory syndrome (PEARS)", The Veterinary Quarterly, Vol. 13, No. 3, July 1991, pp. 131-136.	
		#Timony PJ, "Equine Viral Arteritis", Manual of Standards for Diagnostic Tests and Vaccines, pp. 493-499, 1992.	
		#van Zijl et al., "Live Attenuated Pseudorabies Virus Expressing Envelope Glycoprotein E1 of Hog Cholera Virus Protects Swine against both Pseudorabies and Hog Cholera", <u>Journal of Virology</u> , Vol. 65, No. 5, May 1991, pp. 2761-2765.	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



<sup>1</sup> Unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known 10/750,409 Application Number INFORMATION DISCLOSURE Filing Date December 30, 2003 STATEMENT BY APPLICANT First Named Inventor Meulenberg et al. Group Art Unit To be assigned (use as many sheets as necessary) **Examiner Name** To be assigned 7 2183-4041.4US Sheet of 11 Attorney Docket Number

	ļ	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item	
Examiner Initials *	Cite No. <sup>1</sup>	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#Visser, Nicolaas, "Declaration Of Dr. N. Visser", November 14, 1995, pp. 1-11.	
		#von V. F. Ohlinger et al., "Der »Seuchenhafte Spatabort beim Schwein« - Ein Beitrag zur Atiologie des »»Porcine Reproductive and Respiratory Syndrome (PRRS)««", <u>Tierarztl, Umschau 46</u> , pp. 703-708 (1991).	
		#Waltner-Toews et al., "A Field Trial to Evaluate the Efficacy of a Combined Rotavirus-Coronavirus/Escherichia coli Vaccine in Dairy Cattle", Can J. Comp. Med., 49:1-9, 1985.	
		#Wardley et al., "The Host Response to African Swine Fever Virus", Prog. Med. Virol., Vol. 34, pp.180-192 (1987).	
		#Wenswoort et al., "Antigenic comparison of Lelystad virus and swine infertility and respiratory syndrome (SIRS) virus", <u>J Vet Diagn Invest</u> , Vol. 4, pp. 134-138, 1992.	
		#Wensvoort et al., "Blue ear" disease, The Veterinary Record, Vol. 128, No. 128, June 15, 1991, column 1, letter, page 574.	
		#Wensvoort et al., "Mystery swine disease in the Netherlands: the isolation of Lelystad virus", The Veterinary Quarterly, Vol. 13, No. 3, July 1991, pp. 121-130.	
		#Wensvoort et al., "The Porcine Reproductive and Respiratory Syndrome; Characteristics and diagnosis of the causative virus", Veterinary Biotechnology Newsletter, Vol. 3, pp. 113-120, 1993.	
		#Yoon et al., "Isolation of a cytophathic virus from weak pigs on farms with a history of swine infertility and respiratory syndrome", J. Vet Diagn Invest, 4:139-143 (1992).	
		#ALLENDE, R. et al., North American and European Porcine Reproductive and Respiratory Syndrome Viruses Differ in Non-Structural Protein Coding Regions, Journal Gen. Virol. 80 (Pt 2), 307-315 (1999).	
		#ANDREYEV VG., et al. Abstract, Genetic variation and phylogenetic relationships of 22 porcine reproductive and respiratory syndrome virus (PRRSV) fields strains based on sequence analysis of open reading frame 5, Arch Virol 142:993-1001, 1997.	

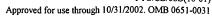
		· · · · · · · · · · · · · · · · · · ·		
1	Examiner		Date	
	Signature		Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



<sup>&</sup>lt;sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of | 11

Complete if Known

Application Number 10/750,409

Filing Date December 30, 2003

First Named Inventor Meulenberg et al.

Group Art Unit To be assigned

Examiner Name To be assigned

Attorney Docket Number 2183-4041.4US

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		#BRAMEL-VERHEIJE et al., Expression of a Foreign Epitope by Porcine Reproductive and Respiratory Syndrome Virus, 2000, Virology, pp. 380-389, Vol. 278.	
		#BOYER, J.C. et al., Infectious Transcripts and cDNA Clones of RNA Viruses, Virology, 1994, pp. 415-426, Vol. 198.	
		#CHEN, Z., et al., Determination of the 5' end of the lactate dehydrogenase-elevating virus genome by two independent approaches, J. Gen. Virol., 1994, pp. 925-930, Vol. 75.	
		#FROLOV et al., Alphavirus-based expression vectors: Strategies and applications, Proceedings of the National Academy of Sciences, 1996, pp. 11371-11377, Vol. 93.	
		#KAPUR, V., et al., Abstract, Genetic Variation in Porcine reproductive and Respiratory Syndrome Virus Isolates in the Midwestern United States, Journal of Gen. Virol. 77, pp. 1271-1276 (1996).	
		#KWANG, Jimmy, et al., Abstract, Cloning, Expression, and Sequence Analysis of the OrF4 Gene of the Porcine Reproductive and Respiratory Syndrome Virus MN-1b, J Vet Diagn. Invest 6, pp. 293-296 (1994).	
		#MARDASSI, H., et al., Abstract, Molecular Analysis of the ORF's 3 to 7 of Porcine Reproductive and Respiratory Syndrome Virus, Quebec Reference Strain, Arch Virol 140, pp. 1405-1418 (1995).	
		#MENG, Xiang-Jin, Abstract, Molecular Cloning and Nucleotide Sequencing of the 3'-Terminal Genomic RNA of the Porcine Reproductive and Respiratory Syndrome Virus, Journal of General Virology 75, pp. 1795-1801 (1994).	
		#MEULENBERG et al., Characterization of Proteins Encoded by ORFs 2 to 7 of Lelystad Virus, Virology, 1995, pp. 155-63, Vol. 206.	
		#MEULENBERG, J.J. M., et al., Lelystad Virus, the Causative Agent of Porcine Epidemic Abortion and Respiratory Syndrome (PEARS), Is Related to LDV and EAV, 1993, Virology, pp. 62-72, Vol. 192.	
		#MEULENBERG, J. J. M., et al., Infectious transcripts from cloned genome-length cDNA of porcine reproductive and respiratory syndrome virus. J. Virol. 72(1):pp. 380-387, 1998.	-
		#MEULENBERG, J.J.M., et al., Abstract, "An infectious cDNA clone of Porcine Reproductive and Respiratory Syndrome Virus" Chapter 24, pp. 199-206 Coronaviruses and Arteriviruses (Advances in Experimental Medicine and Biology, vol. 440),	

Examiner	Date	
Signature	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

> (use as many sheets as necessary) of 11

Sheet

<del></del>	Complete if Known	
Application Number	10/750,409	
Filing Date	December 30, 2003	
First Named Inventor	Meulenberg et al.	-
Group Art Unit	To be assigned	
Examiner Name	To be assigned	
Attorney Docket Number	2183-4041.4US	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
		#KIM HS., et al., Abstract, Enhanced replication of porcine reproductive and respiratory syndrome (PRRS) virus in a homogeneous subpopulation of MA-104 cell line, Arch Virol 133:477-483, 1993.	
		#KREUTZ, L.C. Abstract, "Cellular membrane factors are the major determinants of porcine reproductive and respiratory syndrome virus tropism," Virus Research 53:121-128, 1998.	
		#MENG XJ., et al., Abstract, Phylogenetic analyses of the putative M (ORF 6) and N (ORF 7) genes of porcine reproductive and respiratory syndrome virus (PRRSV): implication for the existence of two genotypes of PRRSV in the U.S.A. and Europe, Arch Virol 140:745-755, 1995.	
		#MOORMANN et al., Infectious RNA Transcribed from an Engineered Full-Length cDNA Template of the Genome of a Pestivirus, Journal of Virology, Feb. 1996, pp. 763-70, Vol. 70, No. 2.	
		#MOROZOV I., et al., Abstract, Sequence analysis of open reading frames (ORFs) 2 to 4 of a U.S. isolate of porcine reproductive and respiratory syndrome virus, Arch Virol 140:1313-1319, 1995.	
·		#MURTAUGH, M. P., et al., Abstract, Comparison of the Structural Protein Coding Sequences of the VR-2332 and Lelystad virus strain of the PRRS virus, Journal Arch. Virol. 140(8), pp. 1451-1460 (1995).	
		#NELSEN, C. J., et al., Porcine reproductive and respiratory syndrome virus comparison: Divergent evolution on two continents. J. Virol. 73 (1): pp. 270-280, 1999.	
		#PCT International Preliminary Examination Report, PCT/NL 00/00152, dated May 29, 2001.	
		#PCT International Search Report, PCT/NL 00/00152, dated July 6, 2000, 3 pages.	
		#ROSSOW KD., Abstract, Porcine Reproductive and Respiratory Syndrome, Vet Pathol 35:1-20 (1998).	
		#SNIJDER et al., The molecular biology of arteriviruses, Journal of General Virology, 1998, pp. 961-79, Vol. 79.	
<del></del>		#SUAREZ P., et al., Abstract, Phylogenetic relationships of European strains of porcine reproductive and respiratory syndrome virus (PRRSV) inferred from DNA sequences of putative ORF-5 and ORF-7 genes, Virus Research 42:159-165, 1996.	
		#TERPSTRA C., et al., Abstract, Experimental reproduction of porcine epidemic abortion and respiratory syndrome (mystery swine disease) by infection with Lelystad virus: Koch's postulates fulfilled, The Veterinary Quarterly, vol. 13, No. 3, pp. 131-136, Jul. 1991.	
		#VAN DINTEN, L.D. et al., 1997, Proc. Natl. Acad. Sci. USA, 94(3):991-996.	
		#ZIMMERMAN JJ., et al., Abstract, General overview of PRRSV: A perspective from the United States, Veterinary Microbiology 55:187-196, 1997.	

Examiner	 Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



<sup>&</sup>lt;sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Complete if Known

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

itute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number 10/750,409

Filing Date December 30, 2003

First Named Inventor Meulenberg et al.

Group Art Unit To be assigned

Examiner Name To be assigned

Attorney Docket Number 2183-4041.4US

Sheet 10 of 11

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#PCT International Preliminary Examination Report, PCT/NL02/00314, dated August 26, 2003, 7 pages.	
		#NC_001961, Porcine reproductive and respiratory syndrome virus, complete genome.	
		#AF066183, Porcine reproductive and respiratory syndrome virus RespPRRS MLV, complete genome.	
		#AF325691, Porcine reproductive and respiratory syndrome virus isolate NVSL 97-7985 IA 1-4-2, complete genome.	
_		#AF176348, Porcine reproductive and respiratory syndrome virus isolate PA8 complete genome.	
		#AF331831, Procine reproductive and respiratory syndrome virus BJ-4, complete genome.	
		#AE005172, Arabidopsis thaliana chromosome 1, top arm complete sequence.	
		#NC_002534, Lactate dehydrogenase-elevating virus, complete genome.	
		#U87392, Porcine reproductive and respiratory syndrome virus strain VR-2332, complete genome.	
		#M96262, Lelystad virus, complete genome.	
		#AF184212, Porcine reproductive and respiratory syndrome virus strain SP, complete genome.	
		#AF159149, Porcine reproductive and respiratory syndrome virus isolate MLV RespPRRS/Repro, complete genome.	
		#AF046869, Porcine reproductive and respiratory syndrome virus isolate 16244B, 2/18/97 (Nebraska)pass.3, complete genome.	
		#U15146, Lactate dehydrogenase-elevating virus Plagemann strain, complete genome.	
		#VIIIth International Symposium on Nidoviruses (Corona and Arteriviruses), May 20-25, 2000.	

Examiner	·	Date	
Signature		Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

of 11

Complete if Known Application Number 10/750,409 December 30, 2003 Filing Date First Named Inventor Meulenberg et al. To be assigned Group Art Unit Examiner Name To be assigned 2183-4041.4US Attorney Docket Number

(use as many sheets as necessary)

Sheet

11

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item Cite  $T^2$ Examiner (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, No.1 Initials \* city and/or country where published. MENGELING et al., Mystery Pig Disease: Evidence and considerations for its etiology, In: Proceedings of the Mystery Swine Disease Committee Meeting, October 6, 1990, Denver, Colorado, Livestock Conservation Institute, Madison, WI, USA. ROTTIER et al., Predicted membrane topology of the coronavirus protein E1, Biochemistry, 1986, pp. 1335 1339, Vol. 25. SETHNA et al., Coronavirus subgenomic minus-strand RNAs and the potential for mRNA replicons, Proc. Natl. Acad. Sci. 1989, USA, pp. 5626 5630, Vol. 86. SPAAN et al., Coronaviruses: structure and genome expression, J. Gen. Virol., 1988, pp. 2939 2952, Vol. 69. VRIES et al., All subgenomic mRNAs of equine arteritis virus contain a common leader sequence, Nucleic Acids Res., 1990, pp. 3241-3247, Vol. 18.

Examiner	Date	
Signature	Considered	

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/874,626

Filed: 6/5/2001

For: INFECTIOUS CLONES OF RNA VIRUSES AND VACCINES AND DIAGNOSTIC ASSAYS DERIVED THEREOF, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



<sup>&</sup>lt;sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.